UpCard

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
II/0005/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue	16/07/2020	n/a		n/a
R/0004	Renewal of the marketing authorisation.	23/04/2020	24/06/2020	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for UpCard.
IA/0003	A.7 - Administrative change - Deletion of manufacturing sites	04/04/2019	n/a		n/a
IG/0842	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	21/09/2017	n/a		n/a

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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IA/0001	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	02/05/2017	n/a		n/a